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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,300	09/11/2003	Masaya Ogura	03599.000076.	3570
5514	7590	01/27/2009	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				SKIBINSKY, ANNA
ART UNIT		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/659,300	OGURA, MASAYA	
	<b>Examiner</b>	<b>Art Unit</b>	
	ANNA SKIBINSKY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 October 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9 and 15-25 is/are pending in the application.
- 4a) Of the above claim(s) 2-7 and 15-25 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,8 and 9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

***DETAILED ACTION***

Applicants' response, filed 10/21/2008, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant's amendments to claim 1 is acknowledged. Claims 1, 8 and 9 are under examination. Claims 10-14 have been cancelled.

***Claim Election/Restriction***

Claims 2-7 and 15-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group and Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 24, 2006.

Claim 25 was withdrawn from examination in the Office Action filed 11/28/2007 as it pertains to the subject matter of the non-elected Groups III in the Election/Restriction requirement filed 3/22/2006.

***Claim Rejections - 35 USC § 101***

1. The following rejection is necessitated by amendments filed 4/28/2008.
2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 8-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1 and 8-9 are drawn to a process for identifying a medical examination device and sharing and utilizing particular information such that the information is separated. The process according the claimed method involves the application of algorithms and computations of carrying out computerized identification and data categorization and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the instant claims must recite a practical application; i.e. recite a useful, concrete, and tangible result. See MPEP 2106, in particular, Section IV, for an explanation of a concrete, tangible and useful result.

Claims 1 and 8-9 do not recite a tangible result. Though the claims recite "permitting a patient to view" information, this is not a tangible result of the method as it does not equate to a patient actually viewing displayed information. The instant limitation may be interpreted as allowing a patient to view information which would mean that the information still resides within the memory of the computer and is therefore not tangible. A tangible result requires that the claim must set forth a practical application to produce a real-world result. Examples of a "real-world result" include a

physical transformation of matter, or a step of communicating the result in a TANGIBLE format to a user; e.g. by outputting or displaying the result of the method. Applicant is reminded that any amendment must be fully supported and enabled by the originally filed description.

As the claims do not recite a physical transformation of matter OR a concrete, tangible and useful result, they are not directed to statutory subject matter.

### ***Response to Arguments***

Applicant's arguments filed 10/21/2008 have been fully considered but they are not persuasive.

Applicants argue that the process involves the transformation of physical objects. The present invention addresses management of information about a medical examination device (MED), e.g. DNA microarray and a device for the inspection using a quartz crystal microbalance reaction. The process of Claim 1 has a medium medical examination device which gets used and whose usage record is maintained. The medical examination device gets transformed e.g., DNA probes hybridize with targets on the DNA microarray.

In response, the instant claims are directed to a method of processing information **about** the medical information device. The processing of information without a useful, concrete, and tangible result is not statutory. Currently, the method as claimed recites the processing of information and lacks a tangible result such a “real-world result” which may include a physical transformation of matter, or a step of

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communicating the result in a TANGIBLE format to a user; e.g. by outputting or displaying the result of the method. A limitation reciting an output of the result of the method in a user readable format would we a tangible result.

***Claim Rejections - 35 USC § 103***

1. The following rejection is necessitated by amendments filed 10/21/2008.
2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
3. Claims 1, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Othmer et al. (US Patent No. 6,167,358; previously cited) in view of Lavin et al. (US Patent No. 5,772,585).
4. The instant claims recite a method for identifying the identification of a medical examination device, writing information related to its usage and correlating the identification of the device with the information related to its usage. The method then shares and utilizes the information about the device with relevant users.
5. Othmer et al. teach a system and method which can be applied to medical examination devices. The method includes detecting information about a computer based system and relaying it back to server which then communicates the information to a plurality of other computer based systems (Abstract).

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6. Claim 1, lines 1-3 and 7-9 recites identifying the identification of a medical examination device and writing down information relating to the usage of the device in a memory.

7. Othmer et al. teaches gathering information about a computer based system over a time interval and transferring the accumulated information back to a central server in order to generate statistics about the frequency of a problem (col. 2, lines 43-52). The system includes generating usage information for each feature in a software application (col. 2, lines 47-49).

8. Claim 1, lines 1-3 and 7-9 and claim 8 recite remotely, through the internet, writing down in memory the additional information related to the usage of the medical examination device.

9. Othmer et al. teaches the server connected remotely to the Internet that permits communication of the computer based systems (col. 4, lines 46-50). The information extracted from the computer based systems which can be medical examination devices such as blood glucose monitor or medical laboratory equipment (col. 4, lines 29-30) is communicated to the server on the network (Abstract and col. 4, lines 43-47).

10. Claim 1, lines 9-10, and claim 9 recite correlating the identification of the device with the additional information such as a lifetime of the device.

11. Othmer et al. teaches that the set of data, called a black box, particular to the device includes a timestamp that determines the sequence of events prior to the triggering of a certain event (col. 5, lines 26-30). The sequence of events is “a lifetime” of events of the device.

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12. Claim 1, lines 10-12 recites “identification of the medical examination device, wherein the particular additional information relates to an inspection result and a usage record of the medical examination device.”

13. Othmer et al. teaches that the timestamp (i.e. additional information) in the black box allows a user to identify events such as a computer crash (col. 5, lines 26-34). The information in the black box is then sent to the developer who can browse/query the information stored (col. 9, lines 13-21) which is thus also related to the usage of the medical device.

14. Claim 1, lines 13-15, recites sharing and utilizing the information about the device among a plurality of users based on the identification.

15. Othmer et al. teach the sharing and utilizing of the device related information with a plurality of users such as customer service databases, email report generator and query tool (col. 9, lines 5-21). A plurality of users may also include a user receiving solution information and a customer support person (col. 2, lines 57-65).

16. Othmer et al. teach a system and method for monitoring a software application on a set of client computers in order to determine information such as defects of usage patterns wherein the system can be medical laboratory equipment (col. 4, lines 19-35). Othmer et al. however do not teach that the sharing and utilizing step further comprises defining and maintaining a division between at least two classes of information stored in the memory, and permitting a patient to view only information in a first of these two classes but not information in the second of these two classes, and permitting at least

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one user other than the patient to view information that is in the second of these two classes, as required by claim 1.

17. Lavin et al. however teach systems with information in separate data files stored on computers and various different databases (col. 1, lines 32-51). Lavin et al. teach that information is organized into categorical tables (col. 4, lines 17-31 and Figure 21)(i.e. defining and maintaining a division between at least two classes of information stored in the memory). Lavin et al. teach that information on medical alerts maybe stored and viewed by the physician (col. 2, lines 1-22) as well as the patient (col. 4, lines 13-15) (i.e. permitting a patient to view only information). Furthermore, the data can be displayed on an interface in an examination room, which would allow the patient to view the information (col. 2, lines 12-15). The information entered by the system user allows the user, such as a healthcare provider, to manipulate the stored information which gives the physician, insurer, or healthcare provider a unique ability to examine the efficiency of medical procedures (col. 2, lines 52-64)(i.e. permitting at least one user other than the patient to view information that is in the second of these two classes).

18. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have implemented the system and method for monitoring a software application on a set of client computers as taught by Othmer et al. the method of storing separate classes of information in tables within one database as taught by Lavin et al. One of skill in the art would have been motivated to use the method of monitoring information taught by Othmer et al. with the method of organizing separate information in separate tables as taught by Lavin et al. because Lavin et al.

teach that the method allows for greater accessibility to separately categorized data while at the same time linking the data together (col. 4, lines 1-8) . One of skill in the art would have had a reasonable expectation of success at the method of Othmer et al. with that of Lavin et al because both teach information and data retrieval as applied to data stored within the memory of a computer.

### ***Response to Arguments***

Applicant's arguments filed 10/21/2008 have been fully considered but they are not persuasive.

Applicant's argue (Remarks, page 14, ¶5-6) that a remote user can directly write relevant information regarding medical examination devices into a central memory without storing such information on the local computer or any computer that might be part of an MED.

In response, instant claim 1 preamble recites that information provided by a plurality of users is remotely writable by these users through a network, into a memory. Instant claim 1 preamble does recite that "a network", which is accessible remotely, is somehow connected to the memory and therefore does not exclude the teachings of Othmer which, as argued by Applicant's includes a nub or separate program executed on client computers (Remarks, page 14, ¶6).

Applicants argue (Remarks, page 15, ¶1) that the teachings of Othmer do not include "a memory into which particular additional information about the medical

examination device provided by some of a plurality of users is remotely writable by these users."

In response, Othmer teaches a system and method for remotely monitoring a plurality of computer based systems connected to a server (Figure 1). As shown in Figure 1, the server (which includes a memory and stores information) is in communication with a plurality of remote computers. Othmer et al. teaches gathering information about a computer based system over a time interval and transferring the accumulated information back to a central server in order to generate statistics about the frequency of a problem (col. 2, lines 43-52).

Applicants argue (Remarks, page 16, ¶2) that Lavin does not teach "said sharing and utilizing step further comprises defining and maintaining a division between at least two classes of information stored in the memory, and permitting a patient to directly access only information in a first of these two classes..." Applicants argue that in the teachings of Lavin et al., a patient is not a user and therefore the teachings of Lavin et al. do not meet the instant limitations.

Lavin et al. teach systems with information in separate data files stored on computers and various different databases (col. 1, lines 32-51) and information organized into categorical tables (col. 4, lines 17-31 and Figure 21)(i.e. defining and maintaining a division between at least two classes of information stored in the memory). Lavin et al. teach that information on medical alerts maybe stored and viewed by the physician (col. 2, lines 1-22) as well as the patient (col. 4, lines 13-15) (i.e. permitting a patient to view only information in a first of these two classes). Lavin et al.

teaches that the method informs patients of medication and allergy problems (col. 4, lines 13-15), and thus suggests that they are users. Furthermore, information pertaining to updating progress notes, automatic reminders, billing information, subjective data, assessments of treatment by the physician (col. 2, lines 1-22) are not available to the patient.

### **Conclusion**

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lori A. Clow/  
Primary Examiner, Art Unit 1631

Anna Skibinsky, Examiner